FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 25, 2019

DRAFT QUESTIONS

---

1. **DISCUSSION**: Discuss the efficacy of nintedanib for treatment of patients with systemic sclerosis interstitial lung disease (SSc-ILD).

    a. Discuss the clinical meaningfulness of the changes in forced vital capacity (FVC) with nintedanib treatment in the popular.

2. **DISCUSSION**: Discuss the FVC data from the following subgroups and the implications for use of nintedanib in patients in the US:

    a. US and Canada subgroup compared to the overall study population
    b. Patients on background mycophenolate versus no background mycophenolate treatment

3. **VOTE:** Overall, do the data provide substantial evidence of the efficacy of nintedanib for the treatment of systemic sclerosis interstitial lung disease?

    a. If no, what further data are needed?

4. **VOTE:** Is the safety profile of nintedanib adequate to support approval of nintedanib for the treatment of systemic sclerosis interstitial lung disease?

    a. If no, what further data are needed?

5. **VOTE:** Do you recommend approval of nintedanib at the proposed dose of 150 mg twice daily for the treatment of systemic sclerosis interstitial lung disease?

    a. If no, what further data are needed?